Section 6: 510(k) Summary

K013661

DEC 0 3 2001

XPlan 2.2 with the BodySystem 510(k) Summary

This summary of the 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. 807.92.

1.0 The submitter of this premarket notification is:

Kevin J. O'Connell
Senior Regulatory Associate
Radionics, a division of Tyco Healthcare Group LP
22 Terry Avenue
Burlington, MA 01803
Tel.: (781) 272-1233
Fax: (781) 272-2428

This summary was prepared on November 2, 2001.

2.0 The name of the device is the Radionics XPlan 2.2 with the Body System. The common name is Stereotactic Radiation Treatment Planning System and Accessories, and its classification name is X-ray radiation therapy system.

3.0 The above device is substantial equivalent to the Radionics XPlan 2.1 Stereotactic Radiation Treatment Planning System Software was cleared via 510(k), K001700, on June 28, 2000 and the Med-Tec (Medical Intelligence) BodyFix System was cleared via 510(k), K001052, on August 30, 2000.

4.0 The above system consists of stereotactic treatment planning software and hardware to immobilize and localize the patient.

5.0 The device like its predicates is intended for use in stereotactic, conformal, computer planned, LINAC (linear accelerator) based radiation. The indications for use are: XPlan 2.2 software is a stereotactic LINAC-based ration treatment planning system. XPlan 2.2 localizes lesions to be treated using CT scans, MR scans, and digitized angiographic film. XPlan 2.2 provides stereotactic planning system for treatment of tumors. The conformal stereotactic radiation therapy treatments are delivered over multiple fractions.

6.0 The technological characteristics are the same or similar to those found with the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 3 2001

Mr. Kevin J. O'Connell
Senior Regulatory Associate
Radionics, a division of
Tyco Health Care Group LP
22 Terry Avenue
BURLINGTON MA 01803

Re: K013661
Trade/Device Name: XPLAN 2.2 With the Body System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 MUJ
Dated: November 2, 2001
Received: November 6, 2001

Dear Mr. O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

ODE Indications for Use Statement

510(k) Number (if known): K013661

Device Name: Radionics XPlan 2.2 with the Body System

Indications for Use:

XPlan 2.2 software is a stereotactic LINAC-based radiation treatment planning system. XPlan 2.2 with the Body System localizes lesions to be treated using CT scans, MR scans, and digitized angiographic film. XPlan 2.2 with the Body System provides stereotactic planning system for treatment of tumors. The conformal stereotactic radiation therapy treatments are delivered over multiple fractions.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use

(Per 21 CFR § 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013661